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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,515	02/07/2006	Andreas Katopodis	ON/4-33306A	1323
1095 NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080	7590 02/04/2008		EXAMINER SIMMONS, CHRIS E	
			ART UNIT 1612	PAPER NUMBER
			MAIL DATE 02/04/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/567,515

Applicant(s)

KATOPODIS, ANDREAS

Examiner

Chris E. Simmons

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 02/07/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

**Status of the claims:** It is acknowledged that the response to an Election/Restriction requirement was filed on 01/03/2008. Accordingly, claims 16-19 and 21-28 are cancelled (claims 1-15 were canceled previously). Claim 20 is presented for examination.

### *Election/Restrictions*

Applicant's election without traverse of Group III (claim 20) in the reply filed on 01/03/2008 is acknowledged. Applicant further made a specie election of the compound, N-hydroxy-3-[4-[[[2-(2-methyl-1H-indol-3-yl)-ethyl]-amino]methyl]phenyl]--2E-2-propenamide.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 20 is rejected under 35 USC 103(a) as being unpatentable over Skov et al. (Blood. 2003 Feb 15;101(4):1430-1438. (Epub 2002 Oct 17.)) in view of Catley et al. (Blood. 2003 Oct 1;102(7):2615-22. (Epub 2003 Jun 19.)).

The primary reference discloses the known fact that histone deacetylase inhibitors are immunosuppressors suggesting they are useful in the therapeutic intervention against autoimmune diseases and allograft rejection (title, abstract). The primary reference does not expressly teach the elected compound, LBH 589.

The secondary reference discloses that NVP-LAQ824 is a potent histone deacetylase inhibitor. The reference does not expressly teach a method of treating graft survival. Its compound differs from the elected compound insofar as NVP-LAQ824 has an H<sup>1</sup> for variable Y and a hydroxylethyl group for variable R<sup>2</sup> but the instant compound has a methyl group for variable Y and a H for variable R<sup>2</sup>.

A prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute LBH 589 for NVP-LAQ824 to increase graft survival with a predictable expectation of successful treatment due to the compounds' structural and functional similarities.

The skilled artisan would have found it obvious at the time of the invention to use a histone deacetylase inhibitor to enhance graft survival following transplantation. The

artisan would have been motivated by a reasonable expectation of success knowing that histone deacetylase inhibitors are useful for such treatments.

2. Claim 20 is rejected under 35 USC 103(a) as being unpatentable over WO 02/022577 (provided in IDS – 02/07/2006) in view of Skov et al. (Blood. 2003 Feb 15;101(4);1430-1438. (Epub 2002 Oct 17.)).

The primary reference discloses hydroxamate compounds, in particular, LBH 589 (compound 200 - page 63), that are inhibitors of histone deacetylase (title, abstract). The primary reference does not expressly teach the use of these compounds to enhance the graft survival following transplantation.

The secondary reference discloses the known fact that histone deacetylase inhibitors are immunosuppressors suggesting they are useful in the therapeutic intervention against autoimmune diseases and allograft rejection (title, abstract). The primary reference does not expressly teach the elected compound, LBH 589.

The skilled artisan would have found it obvious at the time of the invention to use a histone deacetylase inhibitor, such as LBH 589 to enhance graft survival following transplantation. The artisan would have been motivated by a reasonable expectation of success knowing that histone deacetylase inhibitors are useful for such treatments.

### ***Conclusion***

No claims are allowed

The following is pertinent art not relied upon for the current office action:

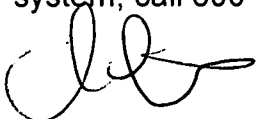
- USP 7199227

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris E. Simmons whose telephone number is (571) 272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Chris Simmons  
Patent Examiner  
AU 1612

Frederick Krass  
Supervisory Patent Examiner  
AU 1612



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